

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

MAUREEN PIEKANSKI

Plaintiff,

v.

ALEX M. AZAR II, in his official
capacity as Secretary of the United
States Department of Health and
Human Services,

Defendant.

No. 3:20-CV-00687

(Judge Mariani)

(Magistrate Judge Carlson)

(Electronically Filed)

**DEFENDANT’S MEMORANDUM OF LAW IN SUPPORT OF HIS CROSS-
MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO
PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT**

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I. INTRODUCTION

Plaintiff Maureen Piekanski suffers from a terrible and deadly form of brain cancer, glioblastoma multiforme (“GBM”). This case involves judicial review of the denial of a Medicare claim for certain months of tumor treatment field therapy (“TTFT”) to treat GBM.¹ Plaintiff raises a single issue on appeal: whether the Secretary of the Department of Health and Human Services (the “Secretary”) is collaterally estopped from denying Plaintiff’s TTFT claim because an administrative law judge (“ALJ”) allowed coverage for certain months of TTFT. But Plaintiff is simply wrong on the law: there is no collateral estoppel here.

Although Plaintiff asserts offensive collateral estoppel against the Secretary, the applicable Medicare statute and regulations expressly prohibit ALJ decisions from having any preclusive effect in future cases. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2)(B); 42 C.F.R. § 405.1062(b). Indeed, the case that Plaintiff principally relies upon in support of collateral estoppel held that preclusion cannot apply when there is a statutory purpose to the contrary, as there is here. *See Astoria Fed. Sav. & Loan Ass’n v. Solimino*, 501 U.S. 104, 108 (1991). The Third Circuit held that the highest level of administrative review, the Medicare Appeals Council (“Council”), “is free to depart from these lower level agency rulings [from

¹ Plaintiff is not financially responsible for paying for the TTFT claim at issue if Medicare does not cover it. *See infra* § II.F.

QICs and ALJs] without concern, as *only its decisions have legal significance.*” *Taransky v. Sec. U.S. Dep’t of Health & Human Servs.*, 760 F.3d 307, 319 (3d Cir. 2014) (emphasis added); *see also John Balko & Assocs., Inc.*, 555 F. App’x 188, 193 (3d Cir. 2014) (holding that the Council’s “review of the ALJ’s findings is *de novo* and [the Council] *is not obligated to defer to the outcomes of prior decisions below.*”) (emphasis added and citation omitted). These Third Circuit holdings directly refute Plaintiff’s collateral estoppel argument, and the Fourth, Fifth, Seventh, Ninth, and D.C. Circuits have also rejected Plaintiff’s assertion that lower-level administrative decisions bind federal agencies. An ALJ decision does not bind the Council just as a district court decision does not bind the Supreme Court. *See Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012).

Furthermore, the elements of collateral estoppel are not present here. First, identical issues were neither previously adjudicated nor actually litigated in Plaintiff’s claim appeals, which concern Medicare coverage for TTFT during different time periods. Second, the controlling facts and legal principles changed significantly in the time between Plaintiff’s claim appeals were decided. Third, it would be unfair to apply collateral estoppel offensively against the Secretary, which was not a party to Plaintiff’s claim appeals. Indeed, it is impracticable for the Secretary to appear as a party in thousands of Medicare claim appeals that are filed each year at the ALJ level. A finding that favorable ALJ decisions

collaterally estop the Secretary would have widespread, negative ramifications for the Secretary and Medicare beneficiaries. The Secretary would be forced to devote Medicare resources to actively litigate thousands of ALJ appeals to avoid the risk of collateral estoppel, thereby taking resources away from tens of millions of Medicare beneficiaries.

Plaintiff fails to identify any case holding that an ALJ's claim determination is binding upon the Secretary in future cases for the same treatment. Meanwhile, the Eastern District of Wisconsin, considering an identical TTFT claim appeal, recently rejected Plaintiff's collateral estoppel argument. *See Christenson v. Azar*, 2020 WL 3642315 (E.D. Wis. July 6, 2020). Because the application of collateral estoppel to ALJ decisions is contrary to the Medicare statute and regulations, Supreme Court precedent, and numerous circuit-level decisions, summary judgment should be granted in the Secretary's favor and Plaintiff's motion for summary judgment should be denied.²

II. STATUTORY AND REGULATORY BACKGROUND

A. "Reasonable and Necessary" Medicare Expenses

Medicare is a federal health insurance program for people who are elderly and/or have disabilities. *See* 42 U.S.C. § 1395. For a medical service to be

² Plaintiff's summary judgment motion only raises the issue of collateral estoppel. Because Plaintiff has abandoned any other grounds to challenge the ALJ decision at issue, the Secretary does not address them.

covered by Medicare, it must fit within a benefit category established by the Medicare statute. *Id.*

This case concerns Medicare Part B, which extends coverage to certain types of durable medical equipment (“DME”) for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6). The various benefit categories available under Medicare Part B are set forth in 42 C.F.R. part 410. Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C.

§ 1395y(a)(1)(A), which excludes certain items from coverage. Under this section, “no payment may be made under . . . part B of this subchapter for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” 42 U.S.C. § 1395y(a)(1)(A). Unless there is an exception, this bar applies “[n]otwithstanding any other provision” of the Medicare statute. 42 U.S.C. § 1395y(a)(1)(A). The Centers for Medicare & Medicaid Services (“CMS”), which administers the Medicare program for the Secretary, has historically interpreted “reasonable and necessary” to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See Medicare*

Program Integrity Manual (“MPIM”) § 13.5.1.³

To administer the “reasonable and necessary” standard, the Secretary employs a range of tools, from formal regulations to informal manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that, “either by default rule or by specification, address every conceivable question” that may arise. *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 96 (1995). The Secretary may articulate “reasonable and necessary” standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also issue National Coverage Determinations (“NCDs”) “with respect to whether or not a particular item or service is covered nationally.” 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060.

B. Enforcement of the “Reasonable and Necessary” Standard Through Local Coverage Determinations (“LCDs”)

The Secretary has delegated to CMS broad authority to determine whether

³ All citations are to the version of the MPIM in effect at the time the 2014 LCD (defined in § II.D.) was issued, which is available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R473PI.pdf> (Transmittal 473, dated 6/21/2013). The MPIM “is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment.” *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

Medicare covers particular medical services.⁴ CMS, in turn, contracts with Medicare Administrative Contractors (“MACs”), such as Noridian Healthcare Solutions in this case, to administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and NCDs, a MAC makes coverage determinations, issues payments, and develops LCDs for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1). *See* 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). An LCD is binding only on the contractor that issued it, and only at the initial stages of the Medicare claim review process, as opposed to later stages if a claimant should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

In developing LCDs, such as the one at issue in this case, MACs follow guidance contained in the MPIM. The MPIM requires MACs to publish LCDs that specify when “an item or service is considered to be reasonable and necessary.” MPIM § 13.1.3. MACs develop LCDs by “considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community.” *Id.*; 66 Fed. Reg. 58,788, 58,788 (Nov. 23, 2001). MACs also follow detailed procedures for issuing new or substantively revised LCDs, including engaging in a comment-and-notice period, soliciting

⁴ *See* 42 U.S.C. §§ 1395y(a), 1395ff(a), (f).

feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.7.4.

C. The Process of Promulgating LCDs

New LCDs require both a notice period and a comment period. MPIM § 13.7.2. The MAC first issues a draft LCD and provides the public a minimum of 45 days to comment on it. LCDs are based on the strongest evidence available, which, in order of preference, includes: (1) Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies; and (2) General acceptance by the medical community (standard of practice), as supported by sound medical evidence. MPIM § 13.7.1. Sound medical evidence should include: (a) scientific data or research studies published in peer-reviewed medical journals; (b) consensus of expert medical opinion (i.e., recognized authorities in the field); or (c) Medical opinion derived from consultations with medical associations or other health care experts. MPIM § 13.7.1. After considering all of the comments and revising the LCD as needed, the contractor publishes the final LCD. *Id.* at § 13.1.3.

D. The LCD for TTFT Devices

In April 2011, the United States Food and Drug Administration approved the marketing of the NovoTTF-100A device (later rebranded Optune) manufactured and supplied to beneficiaries by Novocure, for the treatment of recurrent GBM.

Administrative Record (“AR”) at 2506 [Dkt. No. 33]. Following an open meeting and solicitation of public comments, in August 2014, the MACs issued the original LCD for TTFT (the “2014 LCD”). *Id.* “The DME MACs determined that, based on the strength and quality of the evidence available at that time, TTFT was not reasonable and necessary for the treatment of GBM.” *Id.* The 2014 LCD was in effect at the relevant time, *i.e.*, during the dates of service for the claims on appeal, remained substantively unchanged, and stated that “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” *Id.*; AR at 2577.

In 2018, Novocure requested that the DME MACs approve Medicare payment of TTFT for newly diagnosed GBM. AR at 2506.⁵ Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. AR at 2501-02. Novocure was “extremely pleased” with the 2019 LCD and notes that its coverage criteria “is generally similar to Optune’s commercial coverage criteria for newly diagnosed GBM.”⁶

⁵ Novocure did not submit new evidence in support of revised coverage for recurrent GBM, which was not covered. *Id.*

⁶ See Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, <https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/> (last visited August 27, 2020).

E. Claims and Administrative Appeals

In order for a beneficiary to challenge a denial of a claim under the Medicare statute, he or she must submit a claim for payment to the Medicare contractor, and if the claim is denied, the beneficiary must generally exhaust four levels of administrative review before filing suit in district court. *See generally* 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.904. First, the beneficiary may seek a redetermination from the Medicare contractor, which must be performed by a person who did not make the initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.920, 405.940. An LCD is binding only at this first level of review, and is not binding at any higher level of review 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). At the second level, a beneficiary may seek reconsideration by a qualified independent contractor (“QIC”) whose panel members must have “sufficient medical, legal, and other expertise, including knowledge of the Medicare program.” 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). At the third level, a beneficiary can request a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the administrative record by the ALJ. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

The administrative process ends in a review of the ALJ’s decision by the Council, a division of the Departmental Appeals Board of the Department of

Health and Human Services. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. The Council’s decision (or the ALJ decision, if not reviewed by the Council) represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136. If the Council does not render a decision within a specified time frame, a beneficiary may request elevation to district court. 42 C.F.R. § 405.1132.

The claimant is entitled to judicial review of the Secretary’s decision in the district court “as is provided in [42 U.S.C.] 405(g).” 42 U.S.C. § 1395ff(b)(1)(A). In such review, the Secretary’s findings of fact “if supported by substantial evidence, shall be conclusive.” 42 U.S.C. § 405(g).

F. Advance Beneficiary Notices

If Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing her with advance written notice (called an “Advance Beneficiary Notice”) of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). As the ALJ found, because Novocure did not require Plaintiff to sign an Advance Beneficiary Notice, no matter the outcome of

this case, she will not be financially responsible for the TTFT claim at issue. AR at 2578.

III. PROCEDURAL HISTORY

On January 18, 2019, ALJ Glaze denied Plaintiff's claim for Medicare coverage of certain months of treatment with the Optune system for her GBM. AR at 2578. Plaintiff has fully exhausted her administrative remedies, because the ALJ decision denying her claim became final when the Council did not timely respond to her notice of escalation. AR at 2446-47. Plaintiff filed the instant action instead of awaiting a hearing before the Council. *Id.*

IV. STANDARD OF REVIEW

For appeals arising under section 405(g), a court must uphold an ALJ's findings if they are supported by substantial evidence. *See McGinnis v. Social Security Admin.*, 2020 WL 1623703, at *2 (3d Cir. Apr. 2, 2020); *Rutherford v. Barnhart*, 399 F.3d 546, 552 (3d Cir. 2005). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Rutherford*, 399 F.3d at 552 (citation omitted). It is "more than a mere scintilla but may be somewhat less than a preponderance of the evidence." *Id.* (citation omitted). Review under Section 405(g) is plenary as to the Secretary's application of the relevant law. *Krysztoforski v. Chater*, 55 F.3d 857, 858 (3d Cir.1995).

V. ARGUMENT

A. **The Common Law Doctrine of Collateral Estoppel is Inapplicable to ALJ Decisions in Medicare Claim Appeals**

1. **ALJ decisions expressly do not bind the Secretary in future cases.**

Although Plaintiff primarily bases her collateral estoppel argument on a passage from the U.S. Supreme Court decision in *Astoria*, Pl. Br. at 4-5,⁷ she tellingly omits the very next paragraph, which explains that preclusion cannot apply when there is a statutory purpose to the contrary: “Courts do not, of course, have free rein to impose rules of preclusion, as a matter of policy, when the interpretation of a statute is at hand[,] ... [and] the question is not whether administrative estoppel is wise but whether it is intended by the legislature.” 501 U.S. at 108. The Third Circuit has also held that collateral estoppel may not be applied if it would “frustrate congressional intent or impede the effective functioning of the agency.” *Duvall v. Atty. Gen. of U.S.*, 436 F.3d 382, 387-88 (3d Cir. 2006) (citing *Astoria* at 108-11). Here, the Medicare statute and regulations

⁷ In *Astoria*, the Court considered whether claimants alleging age discrimination under federal law are “collaterally estopped to re-litigate in federal court the judicially unreviewed findings of a state administrative agency made with respect to an age-discrimination claim.” 501 U.S. at 106. The Court held that the state court’s findings had no preclusive effect on federal proceedings. *Id.* Because the federal government was not a party, and the Court found the *absence* of estoppel, Plaintiff’s cited language is mere dicta.

clearly bar the application of collateral estoppel to ALJ decisions.⁸

The Medicare regulations sharply distinguish between a narrow category of precedential decisions that are binding on future administrative appeals and the remainder of non-precedential decisions that are not binding. Only Council-level decisions have the potential to become precedential, which occurs only if they are so designated by the Chair of the Departmental Appeals Board. 42 C.F.R.

§ 401.109. Council decisions designated as precedential must be made available to the public, with personally identifiable information removed, and notice of precedential decisions must be published in the Federal Register. 42 C.F.R.

§ 401.109(b). That decision is then given “precedential effect” and is binding on “all HHS components that adjudicate matters under the jurisdiction of CMS.” *Id.*

§ 401.109(c).⁹

It is undisputed that no Council decision, much less one designated as precedential, has favorably decided Plaintiff’s claims. Accordingly, nothing in the Medicare statute or regulations binds the Secretary to approve Plaintiff’s TTFT treatment. *See Almy*, 679 F.3d at 310 (finding that the Secretary could not have departed from prior precedent because there were no Council-level decisions

⁸ Plaintiff’s reliance on *B & B Hardware, Inc. v. Hargis Indus., Inc.*, is also misplaced, Pl. Br. at 5, because the case involved private parties, and the Court did not consider whether the federal government may be bound by administrative decisions. 575 U.S. 138 (2015).

⁹ HHS is the United States Department of Health and Human Services.

finding that the device at issue was “reasonable and necessary” or “safe and effective”).

ALJ decisions, in contrast, are not capable of having any “precedential effect.” The Medicare regulations define “precedential effect” to mean that:

(1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

(2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. § 401.109(d). Because the lack of “precedential effect” means that any factual findings or legal analysis in ALJ decisions are not binding in future cases, a favorable ALJ decision has no preclusive effect on any future claim. *See* 42 C.F.R. § 401.109(d); *see Taransky*, 760 F.3d at 319 (noting that ALJ decisions do not have legal significance in future cases); *Christenson*, 2020 WL 3642315, at *5 (“ALJ decisions are not binding on another ALJ as only Council-level decisions can carry binding effect.”). As applied here, any factual or legal findings in the ALJ decisions that granted Plaintiff’s TTFT claims would not be binding in any other claim appeals.

To remove any doubt, the regulations re-affirm that only “[p]recedential decisions designated by the Chair of the Departmental Appeals Board in

accordance with § 401.109 of this chapter, are binding” 42 C.F.R.

§ 405.1063(c). Indeed, ALJ decisions are not even binding upon lower levels of administrative review, such as the QIC second level of review. *See* 42 C.F.R.

§ 405.968(b) (omitting ALJ decisions among the rulings that bind the QIC). As the Fourth Circuit notes, “[n]owhere does any policy or regulation suggest that the [Council] owes any deference at all to—much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties merely because they pertain to the same device.” *Almy*, 679 F.3d at 310.

Furthermore, an ALJ’s decision to depart from an LCD and approve coverage “applies only to the specific claim being considered and does not have precedential effect.” 42 C.F.R. § 405.1062(b) (emphasis added); 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005) (“[T]he ALJ or [Council] may decline to follow a policy in a particular case, but must explain the reason why the policy was not followed. These decisions apply only for purposes of the appeal in question, and do not have precedential effect.”). In sum, the Medicare regulations unequivocally reject Plaintiff’s assertion that a prior ALJ decision, which departed from the LCD and approved coverage, collaterally estops the Secretary from denying future claims for coverage.¹⁰

¹⁰ ALJs are not bound by LCDs, but are required to afford them “substantial deference.” 42 C.F.R. § 405.1062(a). ALJs are not authorized to “set aside or

Giving preclusive effect to ALJ decisions is also contrary to the Medicare statute, which provides that the Council must “review the case de novo.” 42 U.S.C. § 1395ff(d)(2)(B) (emphasis added); *see Porzecanski v. Azar*, 943 F.3d 472, 477 (D.C. Cir. 2019) (“Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.”) (citing 42 C.F.R. §§ 401.109, 405.1130, 405.1048). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary’s claim for the same treatment, the Council could not perform a de novo review; instead, the Council would be bound to accept the ALJ’s conclusions. The Third Circuit agrees, noting that “[a]lthough [the Council] is limited to considering only the record before it, its review of the ALJ’s findings is *de novo* and [the Council] ‘is not obligated to defer to the outcomes of prior decisions below.’” *Balko*, 555 F. App’x at 193 (citing *Almy*, 679 F.3d at 310 and section 1395ff(d)(2)(B)). Likewise, in *Taransky*, the Third Circuit rejected plaintiff’s assertion that the Council’s decision was “inconsistent with previous determinations by QICs and ALJs,” holding that the Council “is free to depart from these lower agency rulings without concern, as only its decisions have legal significance.” 760 F.3d at 319.

review the validity of an . . . LCD for purposes of a claim appeal.” *Id.* § 405.1062(c).

Because the Medicare regulations specifically designate ALJ decisions as non-binding and non-precedential, and the application of collateral estoppel is contrary to the Medicare statute, collateral estoppel does not apply. *See Astoria* at 111–12 (rejecting application of collateral estoppel to a federal statute because applying the principle would render a section of that statute superfluous); *Duvall*, 436 F.3d at 387-88.

2. Collateral estoppel on the basis of ALJ decisions would interfere with the discretion and deference afforded to the Secretary to implement the Medicare Statute.

If ALJ decisions were deemed binding, they would interfere with the deference and discretion afforded to the Secretary to implement the Medicare statute’s “reasonable and necessary” standard for coverage of items and services furnished to program beneficiaries. “[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency.” *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute and regulations preserve “this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process.” *Almy*, 679 F.3d at 303. The Supreme Court has foreclosed arguments that interfere with this discretion, holding that “[t]he Secretary’s decision as to whether a particular

medical service is ‘reasonable and necessary’ and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions.” *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *see also Guernsey Mem’l Hosp.*, 514 U.S. at 97 (“The Secretary’s mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.”).

As discussed at length above, nothing in the Medicare statute or regulations indicates that the Secretary intended for favorable ALJ decisions to be given preclusive effect in future cases. The Third Circuit notes “[n]owhere does any policy or regulation suggest that the [Council] owes any deference at all to—much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties.” *Taransky*, 760 F.3d at 319 (quoting *Almy*, 679 F.3d at 310).¹¹ Likewise, in *Hynek v. Astrue*, the court concluded that a statute and regulation that “makes no mention of deference to a prior [ALJ] determination” implied that a favorable ruling should not be given preclusive effect. 2012 WL 460473, at *10 (D. Montana Feb. 13, 2012).

This is for good reason. The Medicare regulations designate ALJ decisions

¹¹ Plaintiff’s discussion of *de novo* review outside the Medicare context is irrelevant. Pl. Br. at 5. The issue here is not the standard for appellate review of a trial court’s order applying collateral estoppel, but rather whether the application of collateral estoppel to ALJ decisions would frustrate the Council’s statutory duty to review such decisions *de novo*.

as non-binding and non-precedential, which allows individual adjudication over Part B claims. Generally speaking, this inures to the benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, have the right to de novo review of any subsequent claims. The application of collateral estoppel, therefore, is fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiff's view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. Pl. Br. at 15-16. Individual adjudication would be impossible, because the Secretary could not review each claim appeal separately and approve or deny it on its own merits. Accordingly, it is within the Secretary's discretion *not* to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607-08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council); *Hunter v. Social Sec. Admin.*, 808 F.3d 818, 822 (11th Cir. 2015) (noting that the deferential review afforded under section 405(g) means that "there is no inconsistency in finding that two successive ALJ decisions are supported by substantial evidence even when those decisions reach opposing conclusions."); *Almy*, 749 F.3d at 310 (concluding that plaintiff's "proposed expansion of what constitutes binding agency precedent would severely constrict the undisputed delegated authority of

the Secretary to administer the Medicare system.”).

Here, the Secretary’s decision that ALJ decisions are non-binding and non-precedential is expressed in the plain, unambiguous language of the applicable law and regulations. *See Avalon Place Trinity*, DAB No. 2819, at 13 (2017) (“An unappealed ALJ decision [does not set] a precedent binding on ALJs or the Board. When the *Board* has not reviewed the ALJ decision, the *Board* has not issued a decision in that case. Regardless of whether an ALJ decision was appealed to the Board, an ALJ decision is not precedential and does not bind the Board, and is relevant in later cases only to the extent its reasoning is on point and persuasive.”) (*italics in original*), *aff’d*, *Avalon Place Trinity v. HHS*, 761 F. App’x 407 (5th Cir. Mar. 4, 2019). Because giving preclusive effect to ALJ rulings would contravene the Medicare regulations, the Court should decline to apply collateral estoppel here.

While Plaintiff fails to cite any cases on point,¹² the Third Circuit (see

¹² Plaintiff’s reliance on the unpublished decision in *Brewster v. Barnhart*, 145 F. App’x 542 (6th Cir. 2005) is misplaced. Pl. Br. at 5. The court found that, under circumstances unique to Social Security disability appeals, an applicant (not the government) was bound by an ALJ’s earlier finding concerning the exertion level of the applicant’s past work. *Id.* at 546-48. Plaintiff’s additional citation, Pl. Br. at 5, to a case concerning the unique circumstances of immigration appeals is similarly unhelpful. *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015). Among other things, unlike the Medicare statute and regulations’ prohibition on collateral estoppel here, the *Islam* court determined that the Immigration and Nationality Act permitted collateral estoppel of issues decided by an Immigration

Taranksy and *Balko*), as well as the Fourth, Fifth, Seventh, Ninth, and D.C. Circuits have each rejected similar attempts to bind federal agencies to non-precedential decisions in lower-level administrative appeals. In *Almy*, plaintiff asserted that Council decisions denying coverage for a medical device created a policy of denying treatment for that device. 679 F.3d at 299. The Fourth Circuit disagreed, noting that “[t]he Secretary’s own regulations make clear that any policy implications in an adjudication do not have precedential effect. . . . The purported ‘policy’ in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage.” *Id.* at 303 (citing 42 C.F.R. § 405.1062). The Fourth Circuit noted that Congress gave the Secretary discretion to “decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year.” *Id.* at 304. Likewise, this Court should reject Plaintiff’s attempt to elevate non-precedential ALJ opinions into binding coverage rules, which would “stultify the administrative process.” *Id.* (quoting *Chenery*, 322 U.S. at 202).

The Fourth Circuit noted that other circuits have concluded that “[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were

Judge in granting asylum. *Id.* at 1093-94. Additionally, unlike here, the other elements of collateral estoppel were actually met in *Islam*. *Id.* at 1091-93.

found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently.” *Id.* at 310 (quoting *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003)). Along the same lines, the D.C. Circuit has emphasized its “well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions.” *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (citing cases). Instead, “a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency.” *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1040 (D.C. Cir. 2008). As applied in this context, the D.C. Circuit found that ALJ decisions are non-precedential and are not binding in subsequent claim determinations. *See Porzecanski*, 943 F.3d at 476, 485; *see also Freeman v. U.S. Dep’t of the Interior*, 37 F. Supp. 3d 313, 344-45 (D.D.C. 2014) (finding that “unappealed” ALJ rulings could not estop the United States because such rulings were not binding on the agency or even on other ALJs and noting that the lack of appeal did not “elevate them to the level of a binding final agency action”).

The Ninth Circuit explicitly adopted the reasoning in *Almy*, reversing a district court decision that “incorrectly measured agency inconsistency across” ALJ decisions. *Int’l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012); *see also County of Los Angeles v. Leavitt*, 521 F.3d 1073, 1079 (9th Cir. 2008) (noting that “intermediary interpretations are not binding on the Secretary,

who alone makes policy”). Likewise, the Seventh Circuit recognized that lower-level decisions may conflict and do not bind the Secretary. *Abraham Memorial Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) (“The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS’s long-standing policy are not determinative. Our precedent instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative.”); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987) (“‘The Secretary’s position’ is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency’s resolution of those disputes. An inconsistent administrative position means flipflops by the agency over time, rather than reversals within the bureaucratic pyramid.”). The Fifth Circuit reached the same conclusion. *See Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) (“[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.”).

In sum, “Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local

contractors cannot deprive her of that discretion, *any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court.*” *Almy*, 679 F.3d at 311 (emphasis added). The doctrine of collateral estoppel cannot transform an ALJ ruling from what is – a decision by an intermediate-level tribunal that is only binding in a single case – to what it is not – an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations and would interfere with the discretion afforded to the Secretary. *See Christenson*, 2020 WL 3642315, at *6 (“In the administrative realm, it is not unreasonable or arbitrary for the Secretary to decide what stage deserves preclusive effect.”).

B. The Elements of Collateral Estoppel are Not Met Here.

Even if ALJ decisions were capable of collateral estoppel effect the elements of collateral estoppel are not present here. The Third Circuit has identified four required elements for the application of collateral estoppel: “(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action.” *Jean Alexander Cosmetics, Inc. v. L’Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (internal quotations omitted). The Third Circuit considers whether the party being precluded “had a full and fair opportunity to litigate the issue in question in the

prior action, . . . and whether the issue was determined by a final and valid judgment.” *Id.* (internal quotation marks and citations omitted). Third Circuit courts also require that the adjudicator at the prior proceeding confronted and decided the question, not merely remarked on it in dicta. *See Khalil v. Rohm & Haas Co.*, 2008 WL 383322, at *14 (E.D. Pa. Feb. 11, 2008) (citing *Hawksbill Sea Turtle v. Fed. Emergency Mgmt. Agency*, 126 F.3d 461, 465 (3d Cir. 1997)). Collateral estoppel generally will not apply when “controlling facts or legal principles have changed significantly since the [prior] judgment.” *Karns v. Shanahan*, 879 F.3d 504, 514 (3d Cir. 2018) (alteration in original) (quoting *Montana, Montana v. United States*, 440 U.S. 147, 155 (1979)).

First, the identical issue was neither previously adjudicated nor actually litigated in Plaintiff’s claim appeals. The sole issue presently on appeal is whether Medicare coverage exists for Plaintiff’s TTFT claims from December 2017 - February 2018. That issue was never litigated in Plaintiff’s November 7, 2018 favorable ruling, which only concerned Plaintiff’s TTFT claims from September - November 2017. Indeed, Plaintiff’s favorable ruling merely concluded that the treatment “provided *on the dates of service* meet Medicare coverage criteria.” AR at 3191 (emphasis added). The ALJ recognized that he was only authorized to decline to follow the LCD for the “particular case” before him. *Id.* at 3190. Because the favorable ruling was expressly limited to a particular time period, and

expressed no opinion about whether coverage might exist for other dates of service, there is no identity of issues between these claim appeals.

Indeed, Plaintiff's choice to file claim appeals meant that any favorable ALJ decision would not have preclusive effect in subsequent cases. If Plaintiff was concerned about re-litigating whether TTFT is a covered Medicare benefit, she could have challenged the LCD or petitioned CMS for a National Coverage Determination under entirely separate channels of review. *See* 42 U.S.C. § 1395y(l) (describing the process of requesting an NCD); 42 C.F.R. § 426.425 (only by raising an LCD challenge can an aggrieved party "state why the LCD is not valid"). Instead, Plaintiff chose to seek the limited relief available in a claim appeal and "cannot circumvent" the "distinct path provided for beneficiaries to secure broader coverage determinations" by asserting that a successful claim appeal has the same broad and binding effect as a local or national coverage determination. *Porzecanski*, 943 F.3d at 486, 486 n.12.

Second, the controlling facts and legal principles changed significantly in the time after Plaintiff's November 7, 2018 favorable claim appeal was decided. The January 18, 2019 unfavorable decision identified recent evidence that Plaintiff's GBM was not newly-diagnosed,¹³ but rather that there was recurrence and/or

¹³ On the other hand, the November 7, 2018 favorable ruling found that Plaintiff's GBM was newly-diagnosed. AR at 3190.

progression. AR at 2577. The ALJ found that “TTFT continued to be used as maintenance therapy during the dates of service at issue without evidence of other treatment options having been trialed, as suggested by the manufacturer and the [National Comprehensive Cancer Network].” *Id.* The ALJ also noted that the pending LCD reconsideration would alter coverage for newly-diagnosed GBM, but would not result in coverage for recurrent GBM. *Id.* Because the ALJ concluded that Plaintiff had developed recurrent GBM, and it is undisputed that TTFT for recurrent GBM is not covered by Medicare, changed circumstances in the facts and law prevent the application of collateral estoppel.

C. It Would be Unfair to Apply Collateral Estoppel Offensively Against the Secretary.

The Supreme Court has granted district courts “broad discretion” to determine when a plaintiff who has met the requisites for the application of collateral estoppel may employ that doctrine offensively. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 331 (1979). The Court explained:

If a defendant in the first action is sued for small or nominal damages, he [or she] may have little incentive to defend vigorously, particularly if future suits are not foreseeable. . . . [If] the application of offensive estoppel would be unfair to a defendant, a trial judge should not allow the use of offensive collateral estoppel.

Id. at 330–31 (citations omitted). Under Third Circuit law, a “finding of fairness to the defendant is thus a necessary premise to the application of offensive collateral

estoppel.” *Raytech Corp. v. White*, 54 F.3d 187, 195 (3d Cir. 1995). It is also “well-settled that the Government may not be estopped on the same terms as any other litigant.” *Community Health Servs.*, 467 U.S. at 60.

In *United States v. Mendoza*, the Supreme Court recognized that “‘the Government is not in a position identical to that of a private litigant,’ both because of the geographic breadth of government litigation and also, most importantly, because of the nature of the issues the government litigates.” 464 U.S. 154, 159 (1984) (quoting *INS v. Hibi*, 414 U.S. 5, 8 (1973) (per curiam)). The Court noted that the government is “party to a far greater number of cases on a nationwide basis than even the most litigious private entity.” *Id.* The government is likely to be involved in lawsuits against different parties that involve the same legal issues – issues that are frequently of substantial public importance. *Id.* at 160.

Accordingly, allowing non-mutual collateral estoppel “would substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue.” *Id.* Rather than receiving the benefit of several courts of appeal decisions, the Supreme Court could only review one final decision before granting certiorari. *Id.*

In addition, the Court approved of the Solicitor General’s discretion when determining whether to appeal. Unlike a private litigant, the Solicitor General “considers a variety of factors, such as the limited resources of the government and

the crowded dockets of the courts, before authorizing an appeal.” *Id.* at 161. The Court concluded that “[t]he conduct of government litigation in the courts of the United States is sufficiently different from the conduct of private civil litigation in those courts so that what might otherwise be economy interests underlying a broad application of collateral estoppel are outweighed by the constraints which peculiarly affect the government.” *Id.* at 162-63.

The policy reasons against collaterally estopping the United States apply with particular force here.¹⁴ The Secretary did not participate in any of Plaintiff’s appeals. Indeed, as in *Parklane* and *Mendoza*, it would not be practicable for the Secretary to defend himself in thousands of ALJ appeals filed each year. *See Christenson*, 2020 WL 3642315, at *7 (“several thousand beneficiary appeals filed annually makes it virtually impossible for the Secretary to be represented at every ALJ-level hearing.”).¹⁵ If the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings, the proceedings simply move forward without the Secretary’s involvement, as they did here. 42 C.F.R. §§ 405.1010(a),

¹⁴ Although the *Mendoza* court noted that its concerns with collateral estoppel against the government “are for the most part inapplicable where mutuality is present,” it did not consider the unique circumstances surrounding Medicare claim appeals. 464 U.S. at 163-64.

¹⁵ *See* 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016); *see, e.g., Am. Hosp. Assoc. v. Azar*, 14-cv-851, Dkt. No. 96 (Mar. 25, 2020 Status Report) (for FY 2018, over 575,000 ALJ appeals pending and over 60,000 ALJ appeals received).

405.1012(b).

Nor would the Secretary have reason to believe that a favorable ALJ ruling could have preclusive effect in future claims, because that outcome would be contrary to the Medicare statute and regulations, Supreme Court precedent, and a number of circuit-level decisions. *See supra* §§ IV.B.1-2. The Medicare appeals process explicitly permits ALJs to reach varying conclusions, and gives the Council discretion to impose uniformity by issuing precedential decisions. As with federal courts, allowing conflicting decisions to percolate up to a higher level improves the decision-making process. *See Mendoza*, 464 U.S. at 160. Finding that an ALJ decision deprives the Secretary of discretion when to make a final determination would be akin to finding that a district court decision could bind the Supreme Court. *See Almy*, 679 F.3d at 310.

The Medicare appeals process is particularly unsuited to the application of collateral estoppel. In *Porzecanski*, the D.C. Circuit held that “stretch[ing] the outcome of a single claim dispute to foreclose a contrary decision in any future determination . . . is at odds with the Medicare regime. . . . Medical science changes. An accepted practice may be obsolete in a few years. Ordering HHS to cover [plaintiff’s] treatments indefinitely can hardly be necessary to effectuate the district court’s judgment regarding one treatment at a particular point in time.” 943 F.3d at 486. Along similar lines, the Fourth Circuit wrote:

[Plaintiff] seeks to impose massive resource costs on the Secretary, requiring her to reverse any decision at a lower level of adjudication either through promulgation of an NCD or through [Council] review lest that lower decision become precedent that precludes a different considered result in future cases before the [Council]. As the Secretary notes, there were 970 million Medicare Part B claims in 2008 alone, and the Secretary rarely participates in the lower level adjudications of those claim determinations. . . . The Secretary has simply not seen fit to invoke her final authority in every case in which there is an argument over whether the evidence adequately supports a finding that a device was “reasonable and necessary.”

Id. at 311 (citations omitted). Accordingly, even assuming that collateral estoppel were legally supportable – which it is not – as a matter of policy, the doctrine of collateral estoppel has no place in Medicare claims appeals and would impose massive costs upon this critical national program and undermine its mission to support the health of the tens of millions of Americans enrolled in Medicare.

The fairness element is also lacking because collateral estoppel could only run against the Secretary – not against the beneficiary. While denial of a beneficiary’s claim has no effect on any future claim, under Plaintiff’s proposal, a single claim approval would forever estop the Secretary from denying future claims. Contrary to decades of Supreme Court precedent, the United States would be *more* susceptible to collateral estoppel than would private litigants. Because the application of collateral estoppel would be fundamentally unfair to the Secretary, it should not be applied here.

D. Plaintiff's Irrelevant Evidence and Argument Outside of the Administrative Record Should be Excluded

The Court's decision in this claim appeal must be based *only* upon the administrative record before the ALJ at the time he rendered the decision on appeal. Plaintiff concedes that judicial review in this case is authorized by 42 U.S.C. § 405(g) (made applicable to the Secretary by 42 U.S.C. 1395ii), which says in the relevant part:

As part of the [Secretary]'s answer the [Secretary] shall file a certified copy of the transcript of the record including the evidence upon which the finding and decision complained of are based. The court shall have power to enter, *upon the pleadings and transcript of the record*, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

(emphasis added); *see* First Amended Complaint [Dkt. No. 27] at ¶ 5, Pl. Br. at 13.

The Supreme Court has held that evidence outside of the administrative record should not be considered. *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943) (“[t]he grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based.”); *Fargnoli v. Massanari*, 247 F.3d 34, 44 n.7 (3d Cir. 2001) (applying *Chenery* in cases arising under section 405(g)). Furthermore, under Third Circuit law, evidence that was not before the ALJ at the time he rendered the decision on appeal must be excluded from the Court's consideration of this case:

[E]vidence that was not before the ALJ cannot be used to argue

that the ALJ's decision was not supported by substantial evidence. . . . No statutory provision authorizes the district court to make a decision on the substantial evidence standard based on the new and material evidence never presented to the ALJ. . . For purposes of judicial review, the "record" is "the evidence upon which the findings and decision complained of are based." 42 U.S.C. § 405(g) (Sentence Three). That is the information that was before the ALJ, the final administrative decisionmaker when the Appeals Council denies review.

Matthews v. Apfel, 239 F.3d 589, 593-94 (3d Cir. 2001).

Citing *Matthews v. Apfel*, this Court found that evidence submitted to the Appeals Council after the ALJ issued his decision was irrelevant. *See Sturges v. Colvin*, 2014 WL 1682021, at *4, *4 n.12 (M.D. Pa. Apr. 28, 2014) (Mariani, J.); *see also, e.g., Johnson v. Berryhill*, 2018 WL 7813741, at *5 (E.D. Pa. Dec. 19, 2018) ("It is well established that evidence that was not before the ALJ cannot be considered by a district court in its determination of whether or not the ALJ's decision was supported by substantial evidence, even if it was submitted to the Appeals Council. The only evidence that may be considered in assessing whether substantial evidence supports the ALJ's decision is the administrative record at the time of the ALJ's decision.").¹⁶

¹⁶ Plaintiff's assertion that a court may take judicial notice of the January 29, 2020 ALJ decision is contrary to this precedent. *See also Baker v. Barnhart*, 457 F.3d 882, 891 (8th Cir. 2006) (holding that the district court abused its discretion by taking judicial notice of evidence outside the administrative record); *Khut v. Astrue*, 2010 WL 545868, at *10 (N.D. Cal. Feb. 12, 2010) (declining to take judicial notice of a subsequent favorable decision). In addition, that ALJ decision

Plaintiff's unfavorable decision on appeal is dated January 18, 2019. The court should exclude her *subsequent* favorable decisions, dated June 4, 2019, September 13, 2019, and January 29, 2020. *See* Exs. D-F to Pl. Br.¹⁷ Because the favorable decisions were issued months *after* the unfavorable decision, they were not part of the administrative record before the ALJ and must be excluded under section 405(g) and Third Circuit law. *See* AR at 3169 (ALJ Exhibit List).

The subsequent favorable decisions should also be excluded as irrelevant to Plaintiff's collateral estoppel argument. The Third Circuit has said that the pendency of an appeal does not prevent the offensive use of a decision for preclusive purposes. *See United States v. 5 Unlabeled Boxes*, 572 F.3d 169, 175 (3d Cir. 2009) ("the pendency of an appeal does not affect the potential for res judicata flowing from an otherwise-valid judgment."). By extension, Plaintiff cannot apply a later ALJ decision to collaterally estop an earlier-decided ALJ decision simply because that earlier case remains pending on appeal.¹⁸

is not a "pleading" under section 405(g) – it is merely a summary judgment exhibit. *See* Pl. Br. at 12.

¹⁷ Plaintiff's reliance on *Opoka v. INS*, 94 F3d 392 (7th Cir. 1996) is also misplaced, because that immigration case did not arise under section 405(g). Pl. Br. at 13-14.

¹⁸ Plaintiff cites no case holding that her subsequent favorable decisions can somehow estop the earlier ALJ decision presently on appeal. Pl. Br at 3. To the contrary, collateral estoppel requires that an issue was "previously adjudicated." *Jean Alexander*, 458 F.3d at 249. A subsequent decision simply cannot "previously adjudicate" an issue. Moreover, Plaintiff's cited cases are inapposite, as they concern concurrent trial court-level litigation.

VI. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court grant his cross-motion for summary judgment and deny Plaintiff's motion for summary judgment.

Respectfully submitted,

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Dated: August 28, 2020

CERTIFICATION BY COUNSEL PURSUANT TO LOCAL RULE 7.8(b)(2)

I, Eric S. Wolfish, hereby certify that this brief, exclusive of the Table of Contents, Table of Authorities, and Signature Block, is less than 35 pages pursuant to the Order dated August 25, 2020.

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney

Dated: August 28, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this date, a true and correct copy of the foregoing Memorandum of Law in Support of the Secretary's Cross-Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment was filed and served upon all counsel of record through the Court's CM/ECF system.

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney

Dated: August 28, 2020